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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/639,615	08/11/2003	Buddy Don Gray	900134.406	5378

500 7590 03/21/2007
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
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SUITE 5400
SEATTLE, WA 98104

EXAMINER

SODERQUIST, ARLEN

ART UNIT	PAPER NUMBER
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1743

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/639,615

Applicant(s)

GRAY, BUDDY DON

Examiner

Arlen Soderquist

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

Art Unit: 1743

1. The disclosure is objected to because of the following informalities: it appears that applicant has incorporated a set of instructions from a brochure or other source that are not in a format for including in the printing. Furthermore, it is not clear what the trademarked compositions are and if that are related to the instant composition/method.

Appropriate correction is required.

2. The use of the trademarks CT01 and TestTab-01 have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

3. Claims 1-8, 10-11 and 17-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the test solution or formulation containing an indicator for the cation and the anion, does not reasonably provide enablement for a test formulation having only an indicator or any other components besides the cation whose binding capacity is being measured. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The invention works based on addition of a sufficient amount of that cation being measured to the sample to determine if the sample can complex or bind the extra cation. Applicant has not taught any other way of determining the binding capacity.

4. Claims 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 12 "said solvent" does not have antecedent basis in claim 7.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 7-9, 11 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Denny (US 4,224,034) or Takano (US 4,588,695).

In the patent Denny teaches assay compositions and methods for measurement of the iron binding capacity of a sample. In particular the example of columns 9-10 is anticipatory.

Art Unit: 1743

In the patent Takano teaches a formulation and method for measuring the ability of a solution (serum) to bind cationic species (iron). Unsaturated iron-binding capacity in serum can be measured colorimetrically rapidly and easily by using an auto analyzer and using a reagent mixture comprising excess iron ions, a reducing agent for iron ions, and a hydroxy acid and/or a salt of a hydroxy acid together with a color-forming reagent solution. Columns 3-7 give several examples of the reagents and method.

7. Claims 7-12, 16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Bauer (US 5,302,531). In the patent Bauer teaches a method, composition and test device for the semiquantitative determination of specific gravity of a test sample. The method utilizes a reagent composition capable of producing a detectable and measurable response that correlates to the concentration of cations, and therefore the specific gravity, of the test sample. The reagent composition, comprises: a) a complexing agent, like a polyelectrolyte, an ion exchange material or a chelating agent, such as a copolymer of maleic acid and methyl vinyl ether; b) a polyvalent metal ion having a valence of at least two, like ferrous ion or cobaltous ion; c) an indicator capable of interacting with the polyvalent metal ion to provide a color transition, like calmagite or galloxyanine; and d) a suitable carrier. The reagent composition is used in a wet phase specific gravity assay or is incorporated into a carrier matrix, like filter paper, to provide a test pad useful in a dry phase specific gravity assay of a test sample, such as urine. Column 13, lines 10-23 teach that any polyvalent metal ion: 1) capable of complexing with the complexing agent, and 2) undergoing a color transition in the presence of the indicator after displacement from the complexing agent, can be included in the reagent composition of the present invention.

Accordingly, a polyvalent metal ion useful in the reagent composition is, for example, but not limited to, ferric ion, ferrous ion, calcium ion, magnesium ion, cobalt(II) ion, cobalt(III) ion, cupric ion, mercuric ion, stannic ion, nickel(II) ion, lead(II) ion, manganese(III) ion, cadmium(II) ion, zinc(II) ion, molybdenum(V) ion, chromium(IV) ion and vanadium(III) ion, or mixtures thereof. Table 1 shows specific indicator reagents for calcium in a pH produced by a 1 N NaOH solution.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1743

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
9. Claims 10 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denny or Takano as applied to claims 1-4, 7-9 and 11 above, and further in view of Fossati (US 5,017,498). Denny and Takano do not teach the reagents in tablet form.

In the patent Fossati teaches indicator compounds and their use in an iron assay system. Column 4, lines 12-26 teach that the reagent combinations can be in the form of a solution or as a powder or are in the form of tablets or a lyophilisate. The reagent combination (if it is not already in the form of a solution) is taken up in water or another suitable solvent and a reagent solution is prepared. If the reagent combination consists of individual components, these are to be mixed with one another. After the sample (for example blood, serum, plasma or urine) has been mixed with an aliquot portion of the reagent mixture, the color formed is measured on a photometer and the concentration of iron is calculated via the molar extinction coefficient and the volumes of reagent and sample added, or via an iron standard aqueous solution.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the reagent of Denny or Takano in an alternate form such as the tablet taught by Fossati because of its ability to be reconstituted prior to mixing with a sample as taught by Fossati.

10. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bauer as applied to claims 7-12, 16 and 18 above, and further in view of Wahl (US 4,871,678). While Bauer teaches the reagent in various forms including solution phase or a test paper, Bauer does not teach a tablet form of the reagent.

Art Unit: 1743

In the paper Wahl teaches a reagent for determining calcium. Column 3 lines 17-25 teach the reagent having an alkaline buffer. Lines 26-31 teach various forms for the reagent including solution, tablet and a paper pad.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the reagent of Bauer in an alternate form such as the tablet taught by Wahl because of its ability to be reconstituted prior to mixing with a sample as taught by Wahl.

11. Claims 1-11, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colombo (US 5,112,905) in view of GB 1296413 and Bauer as explained above. In the patent Colombo teaches transesterified copolymers of maleic anhydride, particularly useful in the field of detergency and anti-scaling agents, obtained from preformed copolymers of maleic anhydride with vinyl acetate, by at least partial transesterification of said preformed copolymers. Column 1 teaches that the action of the sequestering agents in the presence of drinkable water, or of untreated industrial water, is well known. These agents, by formation of complexes with polyvalent metal ions (for instance alkaline-earth metal ions), which form the water hardness, and even with other heavy ions, hinder the formation of precipitates, thus avoiding the scale (incrustation) deposition. In plants where water is warmed, such as boilers or heat-exchangers, the above mentioned agents hinder, as is known, the scale formation on the metal surface. During home-washing and industrial cleaning, polyvalent metal ions may interact with the anions present in the soil and with the anions dissolved by the detergent. In this case also, the scaling (incrustation) action of the mentioned agents on the fabric fibers is known. When control agents are not present, the incrustation would increase the ash contents, washing by washing, thus causing undesired matting and grey coloration phenomena. Column 5 lines 6-24 teach a number of tests used in the examples which follow. As to the methods used for the determination of the parameters mentioned in the examples, further into details of the calcium binding capacity and complexing capacity are found in the following sources. The calcium binding capacity test uses the HAMPSHIRE TEST, mentioned in German Patent No. 1,904,941, corresponding to UK Patent No. 1,296,413. The complexing capacity test to determine the chelating properties was carried out using a calcium ion (Ca^{2+}) selective electrode, as described in ANALYTICAL LETTERS vol. 4 (10); pp. 653-663 (1971). Colombo does not teach using an indicator to measure the calcium.

Art Unit: 1743

In the published application (GB 1,296,413) polymers for use as complexing - agents with metal ions are taught. Relevant to the instant claims is the Hampshire test for determining calcium binding capacity given on page 4, lines 50-73. In this test, the binding capacity is determined by preparing an alkaline buffered sample of the polymer and adding calcium until a permanent color appears.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add an indicator such as taught by Bauer to measure binding capacity because of its ability to measure calcium and provide a clear color differentiation as taught by Bauer (column 1).

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art relates to calcium reagents and their different forms.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571) 272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Arlen Soderquist
Primary Examiner
Art Unit 1743